ARCHIVES
OF
OTOLARYNGOLOGY–
HEAD & NECK SURGERY

May 2005

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JAMA
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JOURNALS
American Medical Association

ORIGINAL ARTICLE

Porous High-Density Polyethylene for Orbital Reconstruction

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Objective: To determine the safety and efficacy of using porous high-density polyethylene (PHDPE) in the repair of orbital defects.

Design: Retrospective case series.

Setting: Academic tertiary care trauma center.

Patients: One hundred seventy patients with orbital defects requiring surgical repair.

Intervention: Orbital defect repair with PHDPE.

Main Outcome Measure: Our review documents surgical results and complications associated with the use of PHDPE.

Results: There was a 6.4% complication rate associated with the use of PHDPE. The infection rate was 1.8%. The persistent orbital malposition rate was 3.5%. The extrusion rate was 0%.

Conclusions: This report represents the largest case series in the literature using PHDPE for orbital reconstructions. The use of PHDPE resulted in a low complication rate and excellent functional and cosmetic reconstructive results. Because of our success with the use of PHDPE, we have changed our clinical practice to minimize the use of autologous graft material, thereby eliminating donor site morbidity in cases involving orbital reconstruction.

Arch Otolaryngol Head Neck Surg. 2005;131:446-450

ORBITAL FRACTURES MAY result in globe malposition and restriction of ocular movement, causing diplopia and impairing vision. Reconstruction of orbital wall defects is required to maintain globe position and unrestricted ocular motility in cases involving large defects or entrapment of orbital tissue. Autograft materials have been shown to be a reliable method for repairing orbital defects. Autogenous implants, particularly cranial bone and nasal septal cartilage, have been advocated because of their resistance to the infections that can be caused by long-term exposure to organisms of the paranasal sinuses. However, harvesting autogenous grafts increases operative time and, depending on the graft location, is associated with the potential of serious donor site morbidity. Adapting these relatively flat and inflexible grafts to the complex contours of the orbit without compromising their integrity may also prove difficult.

Alloplastic materials also have been used to reconstruct orbital defects.[1] Alloplastic materials are easier to mold into the desired shape, but their use in orbital reconstruction has the potential for increased risk of infection. Implant migration may require implant removal. Of the many alloplasts that are available, we have increasingly used porous high-density polyethylene (PHDPE) (Medpor; Porex Surgical Inc, College Park, Ga) to repair orbital defects. Porous high-density polyethylene is a nonreactive material that allows vascular and soft tissue ingrowth, which is thought to enhance stabilization of the implant and promote resistance to infection. Our goals were to document and analyze any complications directly related to the use of PHDPE that required revision surgery and to establish guidelines for the use of this alloplastic material in orbital reconstruction.

METHODS

We performed a retrospective review (institutional review board No. 03-9315-E 01, Human Subjects, University of Washington, Seattle) of 170 cases in which PHDPE was used for the reconstruction of orbital defects at Harborview Medical Center, Seattle, from March

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Financial Disclosure: None.

1998 to October 2003. All patients underwent an ophthalmologic examination before surgery, the extent of which depended on the patient's neurologic status. We examined the size, location, and cause of the defect; the preoperative signs and symptoms; the procedure performed; the type and number of PHDPE implants used, and the postoperative outcomes. Patients who did not undergo a follow-up examination at least 6 weeks after their surgery were not included in the study.

RESULTS

Porous high-density polyethylene was placed into 190 orbits in 170 patients. One hundred sixty-five patients (97.1%) were treated for traumatic injuries, 12 (7.3%) of which were delayed reconstructions (>6 weeks from time of injury). The remaining 5 patients (2.9%) underwent tumor extirpation that resulted in a bony orbital defect. Of the 165 patients with traumatic injuries, 80 (48.5%) had an orbitozygomaticomaxillary fracture or a Le Fort II/III fracture variant. Fifty patients (30.5%) had an isolated orbital floor injury, while the remaining 35 patients (21.2%) had panfacial or bilateral fractures. Fifty-six (33.9%) of the patients with traumatic injuries presented with acute or delayed enophthalmos, 84 (50.9%) presented with restriction of ocular movement, and 30 (18.2%) presented with both enophthalmos and restriction of ocular movement. Twenty-two patients (13.3%) had normal results on their ocular examination but had evidence of involvement of more than 50% of the orbital floor on computed tomographic scans. Twenty-eight patients (17%) could not be fully examined because their neurologic status precluded an accurate assessment of ocular motility (forced duction testing was not performed). All 5 patients with tumors exhibited signs of proptosis and limited ocular motility.

One hundred forty defects (73.7%) involved the inferior orbital floor, 35 (18.4%) the medial orbital wall, 14 (7.4%) the lateral orbital wall, and 1 (0.5%) the superior orbital wall. In 35 patients (20.5%), PHDPE was used to repair orbital defects that encompassed more than 1 orbital wall. The majority of the inferior, medial, and lateral orbital wall defects were approached through a transconjunctival incision. Endoscopic-assisted repair of inferior orbital floor defects through a Caldwell-Luc approach was successful in 20 (87.0%) of 23 patients (**Figure 1** and **Figure 2**). A transconjunctival approach was successfully used for placement of the implant in the cases in which the endoscopic attempt at repair failed. Medial orbital wall fractures that were inaccessible through a transconjunctival approach were repaired via multiple other approaches, including 1 transcaruncular approach and 2 Lynch incisions, while the remaining orbital defects were approached through a coronal incision for panfacial trauma or existing lacerations. The superior orbital roof implant was placed via a Lynch incision.

All patients had been given preoperative steroids (dexamethasone, 10 mg) and a broad-spectrum antibiotic. In all, 205 implants were used to repair 190 orbital defects. None of the implants were soaked in antibiotic solution before insertion. One hundred forty implants were single-sheet nonchanneled PHDPE: 90 (39.8%) were 0.4 mm in thickness, 50 (24.8%) were 0.85 mm in thickness, and

Figure 1. Endoscopic approach depicting isolation of orbital defect before placement of porous high-density polyethylene (Medpor; Porex Surgical Inc, College Park, Ga) implant.

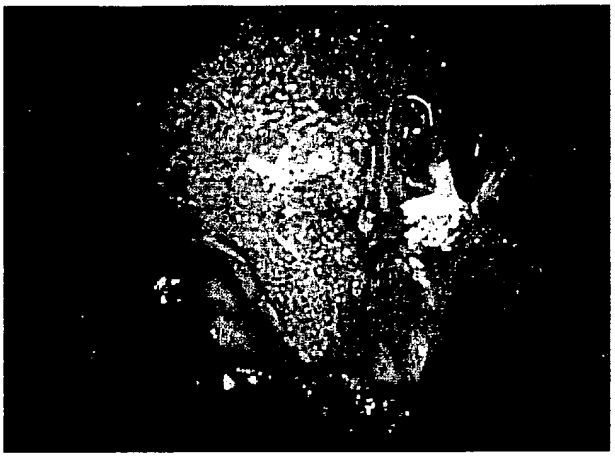

Figure 2. Successful placement of porous high-density polyethylene (Medpor; Porex Surgical Inc, College Park, Ga) implant to repair inferior orbital defect via endoscopic approach.

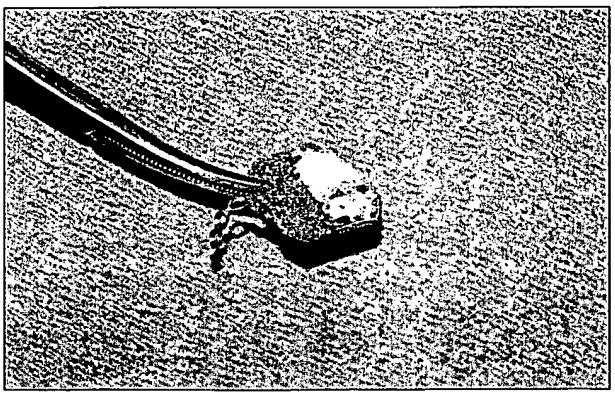

Figure 3. A 1.0-mm titanium miniplate in single-channel porous high-density polyethylene (Medpor; Porex Surgical Inc, College Park, Ga) implant before implantation.

14 (6.8%) were 1.0 mm in thickness. Thirty-nine implants (24.0%) were single-channel PHDPE implants (0.85 mm in thickness) (**Figure 3** and **Figure 4**), and 12 (9.0%) were multichannel PHDPE implants (2.3 mm in thickness). The majority of the surgeons did not use any form of fixation for the nonchanneled implants or close

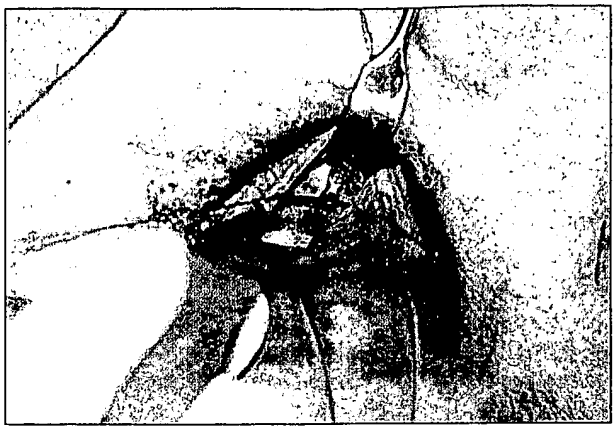

Figure 4. Single-channel porous high-density polyethylene (Medpor; Porex Surgical Inc, College Park, Ga) implant cantilevered off left inferior orbital rim to repair inferior orbital defect viewed superiorly.

the periosteum of the orbital rim after placement of the implant. One surgeon placed a single screw anteriorly to hold the implant when a channeled implant was not used and closed the periosteum over the implant when possible. One-millimeter titanium plates (Synthes, Paoli, Pa) were used to cantilever the channeled implants from the orbital rim.

The average length of follow-up for all patients was 7.4 months. Complications were noted in 11 (6.4%) of the 170 patients. One case of blindness resulted from a retrobulbar hematoma due to uncontrolled hypertension, despite an emergent canthotomy, removal of implant, and evacuation of the hematoma. The displacement of 2 implants (both 0.4 mm in thickness, unfixed, and placed through a modified transconjunctival approach) resulted in obstruction of the maxillary ostia, causing maxillary sinusitis. The implants were removed, with no further sequelae. Interestingly, neither of the patients involved had any evidence of enophthalmos. There was 1 case of an infected single-channel implant (with a 1.0-mm titanium miniplate placed through a standard transconjunctival approach), with an orbital abscess requiring removal and drainage. There were 7 cases of persistent enophthalmos after primary repair that required revision. Three of our patients with persistent enophthalmos were found to have slipped implants (2 single-channel and 1 nonchanneled) at the time of reoperation; replacing these implants in their anatomical position corrected the enophthalmos. One of the 3 patients experienced a second trauma to the surgical site a few weeks after his primary repair. The rest of our cases of enophthalmos were thought to be attributable to inadequate re-creation of the posterior orbital volume, cicatricial scarring, or orbital fat atrophy due to trauma. These cases of enophthalmos were corrected by medial and lateral augmentation of the orbital walls with PHDPE or by re-creation of the posterior convexity of the orbital floor with stacked sheets of PHDPE. The rest of our patients had resolution of any enophthalmos and/or ocular movement restriction that had been present before surgery. There were 3 cases of ectropion and 1 case of entropion, 2 of which required surgical revision. The single case of entropion occurred after a formal lateral canthotomy incision, while the other cases of eyelid malposition occurred after the modified transconjunctival approach. All of these cases involved nonchanneled PHDPE. However, all of these cases had comminuted orbital rim defects that were repaired with titanium miniplates.

COMMENT

Medpor is formed by sintering small particles of high-density polyethylene to create strong, firm material that can be molded by hot water. It maintains its shape because it does not disrupt the overall macromolecular structure of the implant. Pore sizes range from 100 to 250 μm (50% are larger than 150 μm). This porous material allows fibrovascular ingrowth into the implant, preventing capsule formation and promoting stabilization of the implant.[2] Foreign bodies have been shown to reduce the number of bacteria required to produce infection by a factor of 10^4 to 10^6.[3] Recent studies have shown that because of the increased fibrovascularization, PHDPE is more resistant to infection than another porous allograft material, expanded polytetrafluoroethylene.[4] Immediate infections are thought to occur more often with porous alloplastic material because of the increased surface area associated with the porous material. However, the increase in surface area makes the implant more resistant to late infections because fibrovascularization of the implant allows increased immune response mediators at the site.[5] This fibrovascularization is evidenced by the ability of computed tomography and magnetic resonance imaging to show enhancement of PHDPE radiographically.[6] Also, experimentally exposed porous polyethylene that has been invaded by fibrovascular tissue has shown the ability to support skin grafts and promote healing by secondary intention in rats.[7] The fibrovascularization not only protects the implant from infection but also prevents its migration.[8] Theoretically, speeding up the time for fibrovascularization may enhance the early stability of the implant as well as its resistance to infection. Autologous blood clot, epidermal growth factor, and basic fibroblast growth factor have been found to speed fibroblast incorporation into the PHDPE implants after 2 weeks of implantation in rats.[9-11]

In our experience, PHDPE has been used to repair orbital defects successfully, with a very low complication rate, and most of the complications that did occur were not related to the implant itself. There was 1 case of orbital abscess associated with the implant, but a titanium plate or devitalized tissue may also have been a source of infection. Considering that the majority of our implants were placed in the setting of exposed sinus contents, the rate of infection was remarkably low. We do not soak our implants in antibiotic solution, as some authors recommend. Maxillary sinusitis is common after midface fractures,[12] but when an implant has been placed, infected plates and/or slipped implants should be considered as possible sources of nonresolving sinusitis. We can conclude that the use of PHDPE results in a very low rate of infection and that presoaking the implants in an antibiotic solution is unnecessary.

One potential key to the use of PHDPE is to ensure fixation of the implant to avoid displacement, which may result in obstruction of the maxillary sinus ostia, globe malposition, restriction of gaze, or direct pressure on the optic nerve from posterior displacement. We have transitioned our practice somewhat, using an increasing number of the single-channel implants fixated to the orbital rim to ensure stability of the implant. Placing cantilevered implants in the presence of an orbital rim fracture requires planning to prevent the cantilevered plate from crossing the orbital rim fixation plate if at all possible. Overlapping the orbital rim plate with the cantilevered plate can result in the plates being more readily palpable and may cause destabilization of the microplate that is attached to the PHDPE implant. Placing a screw anteriorly to fixate the implant is a useful technique, but it is not always possible, particularly if the rim is comminuted. Likewise, closing the periosteum over the rim may help secure the implant but also is not possible in every case. Multichannel implants are used when more than 1 orbital wall is re-created, when 2-plate fixation is needed for implant stability, or when a very thick piece of porous polyethylene is required. The use of multichannel implants in this manner has been reported to be successful and has not been associated with an increased infection or complication rate.[13,14] We, too, have not found an increased complication rate associated with multichannel implants. We have had excellent results without fixation of the implant, presumably because of fibrovascularization of the implant. We should note that none of our patients who had a successful endoscopic repair of an orbital floor defect have experienced postoperative complications due to a lack of fixation of the implant. Two of our patients with persistent enophthalmos had displaced single-channel implants. Despite fixation of the implant to the anterior orbital rim, at least 1 adequate posterior, medial, or lateral ledge is still required to help support the orbital contents. It is likely that the implants were not adequately positioned during the initial operation.

There have been other retrospective reviews that have examined the use of PHDPE for orbital defect repair (**Table**).[13,15-24] Porous high-density polyethylene has an extremely reliable track record in terms of infection. Our study does have some limitations. We did not formally measure enophthalmos with an exophthalmometer at the time of surgery. Correlating preoperative signs and symptoms with postsurgical outcomes is difficult in patients with traumatic injuries because most of them undergo surgery within 2 weeks of their acute injury. Therefore, continued edema limited our ability to determine the exact degree of enophthalmos and restriction of eye movement. Also, the follow-up period for most of our patients was relatively short. For complete assessment of the accuracy of re-creating orbital volume and prevention of enophthalmos, as well as resistance to implant extrusion and infection, longer-term follow-up is required. We can state that when the acute swelling due to the procedure has subsided, our results have been excellent, at least in the short term.

In general, as a matter of personal preference we do not use PHDPE to re-create the medial orbital walls in cases of panfacial trauma involving the skull base with exposed dura. Despite repair of the skull base defect with a pericranial flap, the proximity of the implant to the dura and paranasal sinuses concerns us. In such cases, a coronal flap is almost always indicated and harvesting cranial bone graft is easily performed. We also prefer to use cranial bone graft for reconstruction of our significant temporal and orbital defects after sphenoid wing or orbital tumor resections with exposed dura or brain.

In conclusion, porous high-density polyethylene is a safe and effective tool for use in craniomaxillofacial reconstruction. Overall, it is an excellent alternative to autogenous grafts, and its use results in decreased operative time and morbidity. In our series, the infection rate was very low and there were no problems with extrusion.

Table. Review of Porous High-Density Polyethylene for Orbital Reconstruction

Source	No. of Patients	% (No./Total No.) Infection Rate	% (No./Total No.) Persistent Globe Malposition
Chen and Chen[20]	3	0	0
Choi et al[19]	32	3.1 (1/32)	3.1 (1/32)
Folkestad and Granstrom[23]	44	0	19.0
Goldberg et al[24]	4	0	0
Hwang and Kita[22]	6	0	0
Ng et al[15]	30	3.3 (1/30)	3.3 (1/30)
Romano et al[18]	140	0.7 (1/140)	1.4 (2/140)
Rubin et al[17]	37	2.7 (1/37)	2.7 (1/37)
Villarreal et al[16]	32	12.5 (4/32)	37.5 (9/24)
Wellisz et al[21]	15	0	0
Yaremchuk[8]	145	0	0
Present study	170	1.8 (3/170)	3.5 (6/170)

Submitted for Publication: October 14, 2004; accepted February 3, 2005.
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Previous Presentation: This study was presented at the AO ASIF (Association for Internal Fixation) Advanced Craniomaxillofacial Trauma Course; February 8, 2004; Sun Valley, Idaho.

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